



# Senate

General Assembly

**File No. 450**

January Session, 2005

Substitute Senate Bill No. 1207

*Senate, April 20, 2005*

The Committee on Public Health reported through SEN. MURPHY of the 16th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

## **AN ACT CONCERNING THE CAPITAL EXPENDITURE THRESHOLD FOR THE REGULATION OF EQUIPMENT ACQUISITIONS.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Subdivision (4) of subsection (a) of section 19a-638 of the  
2 general statutes is repealed and the following is substituted in lieu  
3 thereof (*Effective July 1, 2005*):

4 (4) [Each] Except as provided in sections 19a-639a to 19a-639c,  
5 inclusive, as amended by this act, each applicant, prior to submitting a  
6 certificate of need application under this section, section 19a-639, as  
7 amended by this act, or under both sections, shall submit a request, in  
8 writing, for application forms and instructions to the office. The  
9 request shall be known as a letter of intent. A letter of intent shall  
10 include: (A) The name of the applicant or applicants; (B) a statement  
11 indicating whether the application is for (i) a new, replacement or  
12 additional facility, service or function, (ii) the expansion or relocation  
13 of an existing facility, service or function, (iii) a change in ownership or

14 control, (iv) a termination of a service or a reduction in total bed  
15 capacity and the bed type, (v) any new or additional beds and their  
16 type, (vi) a capital expenditure over one million dollars, (vii) the  
17 [acquisition] purchase or lease of major medical equipment [, imaging  
18 equipment or a linear accelerator costing over four hundred thousand  
19 dollars] costing over four hundred thousand dollars, (viii) a CT  
20 scanner, PET scanner, PET/CT scanner, MRI scanner, cineangiography  
21 equipment, a linear accelerator or other equipment utilizing  
22 technology that is new or being introduced into the state, or (ix) any  
23 combination thereof; (C) the estimated capital cost, value or  
24 expenditure; (D) the town where the project is or will be located; and  
25 (E) a brief description of the proposed project. The office shall provide  
26 public notice of any complete letter of intent submitted under this  
27 section, section 19a-639, as amended by this act, or both, by publication  
28 in a newspaper having a substantial circulation in the area served or to  
29 be served by the applicant. Such notice shall be submitted for  
30 publication not later than fifteen business days after a determination  
31 that a letter of intent is complete. No certificate of need application will  
32 be considered submitted to the office unless a current letter of intent,  
33 specific to the proposal and in compliance with this subsection, has  
34 been on file with the office at least sixty days. A current letter of intent  
35 is a letter of intent [which] that has been on file at the office up to and  
36 including one hundred twenty days, except that an applicant may  
37 request a one-time extension of a letter of intent of up to an additional  
38 thirty days for a maximum total of up to one hundred fifty days if,  
39 prior to the expiration of the current letter of intent, the office receives  
40 a written request to so extend the letter of intent's current status. The  
41 extension request shall fully explain why an extension is requested.  
42 The office shall accept or reject the extension request [within] not later  
43 than five business days from the date it receives such request and shall  
44 so notify the applicant.

45 Sec. 2. Subsection (a) of section 19a-639 of the general statutes is  
46 repealed and the following is substituted in lieu thereof (*Effective July*  
47 *1, 2005*):

48 (a) Except as provided in sections 19a-639a to 19a-639c, inclusive, as  
49 amended by this act, each health care facility or institution, including,  
50 but not limited to, any inpatient rehabilitation facility, any health care  
51 facility or institution or any state health care facility or institution  
52 proposing (1) a capital expenditure exceeding one million dollars, [or  
53 the acquisition] (2) to purchase, lease or accept donation of major  
54 medical equipment requiring a capital expenditure, as defined in  
55 regulations adopted pursuant to section 19a-643, in excess of four  
56 hundred thousand dollars, or (3) to purchase, lease or accept donation  
57 of a CT scanner, PET scanner, PET/CT scanner, MRI scanner,  
58 cineangiography equipment, a linear accelerator or other equipment  
59 utilizing technology that is new or being introduced into this state,  
60 including the [leasing] purchase, lease or donation of equipment or a  
61 facility, shall submit a request for approval of such expenditure to the  
62 office, with such data, information and plans as the office requires in  
63 advance of the proposed initiation date of such project.

64 Sec. 3. Subdivision (3) of subsection (b) of section 19a-639 of the  
65 general statutes is repealed and the following is substituted in lieu  
66 thereof (*Effective July 1, 2005*):

67 (3) The office shall comply with the public notice provisions of  
68 subdivision (4) of subsection (a) of section 19a-638, as amended by this  
69 act, and shall hold a public hearing with respect to any complete  
70 certificate of need application filed under this section, if: (A) The  
71 proposal has associated total capital expenditures or total capital costs  
72 that exceed twenty million dollars for land, building or nonclinical  
73 equipment acquisition, new building construction or building  
74 renovation; [or] (B) the proposal has associated total capital  
75 expenditures per unit or total capital costs per unit that exceed one  
76 million dollars for the purchase or lease of major medical equipment; [,  
77 imaging equipment or] (C) the proposal is for the purchase or lease of  
78 scanning equipment, cineangiography equipment, a linear accelerator  
79 [.] or other equipment utilizing technology that is new or being  
80 introduced into the state; or [(C)] (D) three individuals or an individual  
81 representing an entity comprised of five or more people submit a

82 request, in writing, that a public hearing be held on the proposal. At  
83 least two weeks' notice of such public hearing shall be given to the  
84 applicant, in writing, and to the public by publication in a newspaper  
85 having a substantial circulation in the area served by the applicant. At  
86 the discretion of the office, such hearing shall be held in Hartford or in  
87 the area so served or to be served.

88 Sec. 4. Subsection (c) of section 19a-639 of the general statutes is  
89 repealed and the following is substituted in lieu thereof (*Effective July*  
90 *1, 2005*):

91 (c) [Notwithstanding section 19a-639a or 19a-639b, each] Each  
92 person or [facility] provider, other than a health care or state health  
93 care facility or institution subject to subsection (a) of this section,  
94 proposing to [acquire] purchase, lease, accept donation of or replace  
95 [imaging equipment or a linear accelerator, requiring a capital  
96 expenditure, as defined in regulations adopted pursuant to section  
97 19a-643, in excess of four hundred thousand dollars, including the  
98 leasing or donation of such equipment and facility and including all  
99 capital expenditures, as defined in regulations adopted pursuant to  
100 said section, associated with the provision of the imaging service or  
101 operation of a linear accelerator] (1) major medical equipment with a  
102 capital expenditure in excess of four hundred thousand dollars, or (2) a  
103 CT scanner, PET scanner, PET/CT scanner, MRI scanner,  
104 cineangiography equipment, linear accelerator or other equipment  
105 utilizing technology that is new or being introduced into the state,  
106 shall submit a request for approval of any such [imaging equipment or  
107 linear accelerator acquisition] purchase, lease, donation or replacement  
108 pursuant to the provisions of subsection (a) of this section. In  
109 determining the capital cost or expenditure for an application under  
110 this section or section 19a-638, as amended by this act, the office shall  
111 use the greater of [(1)] (A) the fair market value of the equipment as if  
112 it were to be used for full-time operation, whether or not the  
113 equipment is to be used, shared or rented on a part-time basis, or [(2)]  
114 (B) the total value or estimated value determined by the office of any  
115 capitalized lease computed for a three-year period. Each method shall

116 include the costs of any service or financing agreements plus any other  
117 cost components or items the office specifies in regulations, adopted in  
118 accordance with chapter 54, or deems appropriate.

119 Sec. 5. Section 19a-639a of the general statutes is repealed and the  
120 following is substituted in lieu thereof (*Effective July 1, 2005*):

121 (a) Except as provided in subsection (c) of section 19a-639, as  
122 amended by this act, or as required in subsection (b) of this section, the  
123 provisions of section 19a-638, as amended by this act, and subsection  
124 (a) of section 19a-639, as amended by this act, shall not apply to: (1) An  
125 outpatient clinic or program operated exclusively by, or contracted to  
126 be operated exclusively for, a municipality or municipal agency, a  
127 health district, as defined in section 19a-240, or a board of education;  
128 (2) a residential facility for the mentally retarded licensed pursuant to  
129 section 17a-227 and certified to participate in the Title XIX Medicaid  
130 program as an intermediate care facility for the mentally retarded; (3)  
131 an outpatient rehabilitation service agency that was in operation on  
132 January 1, 1998, that is operated exclusively on an outpatient basis and  
133 that is eligible to receive reimbursement under section 17b-243; (4) a  
134 clinical laboratory; (5) an assisted living services agency; (6) an  
135 outpatient service offering chronic dialysis; (7) a program of  
136 ambulatory services established and conducted by a health  
137 maintenance organization; (8) a home health agency; (9) a clinic  
138 operated by the Americares Foundation; (10) a nursing home; or (11) a  
139 rest home. [However, the] The exemptions provided in this section  
140 shall not apply when a nursing home or rest home is, or will be  
141 created, acquired, operated or in any other way related to or affiliated  
142 with, or under the complete or partial ownership or control of a facility  
143 or institution or affiliate subject to the provisions of section 19a-638, as  
144 amended by this act, or subsection (a) of section 19a-639, as amended  
145 by this act.

146 (b) Each health care facility or institution exempted under this  
147 section shall register with the office by filing the information required  
148 by subdivision (4) of subsection (a) of section 19a-638, as amended by

149 this act, for a letter of intent at least ten business days but not more  
150 than sixty calendar days prior to commencing operations and prior to  
151 changing, expanding, terminating or relocating any facility or service  
152 otherwise covered by section 19a-638, as amended by this act, or  
153 subsection (a) of section 19a-639, as amended by this act, or covered by  
154 both sections or subsections, except that, if the facility or institution is  
155 in operation on June 5, 1998, said information shall be filed not more  
156 than sixty days after said date. Not later than ten business days after  
157 the office receives a completed filing required under this subsection,  
158 the office shall provide the health care facility or institution with  
159 written acknowledgment of receipt. Such acknowledgment shall  
160 constitute permission to operate or change, expand, terminate or  
161 relocate such a facility or institution or to make an expenditure  
162 consistent with an authorization received under subsection (a) of  
163 section 19a-639, as amended by this act, until the next September  
164 thirtieth. Each entity exempted under this section shall renew its  
165 exemption annually by filing current information each September.

166 (c) Each health care facility or institution that proposes to purchase  
167 or lease a CT scanner, PET scanner, PET/CT scanner, MRI scanner,  
168 cineangiography equipment or a linear accelerator shall be exempt  
169 from certificate of need review pursuant to sections 19a-638 and 19a-  
170 639, as amended by this act, if such facility or institution (1) provides  
171 to the office satisfactory evidence that it purchased or leased such  
172 equipment on or before July 1, 2005, and such equipment was in  
173 operation on or before said date, or (2) obtained, on or before July 1,  
174 2005, from the office, a certificate of need or a determination that a  
175 certificate of need was not required for the purchase or lease of such  
176 equipment.

177 Sec. 6. Section 19a-639c of the general statutes is repealed and the  
178 following is substituted in lieu thereof (*Effective July 1, 2005*):

179 Notwithstanding the provisions of section 19a-638, as amended by  
180 this act, or section 19a-639, as amended by this act, the office may  
181 waive the requirements of those sections and grant a certificate of need

182 to any health care facility [.] or institution or provider or any state  
 183 health care facility [.] or institution or provider proposing to replace  
 184 major medical equipment, [imaging equipment] a CT scanner, PET  
 185 scanner, PET/CT scanner, MRI scanner, cineangiography equipment  
 186 or a linear accelerator if:

187 (1) The health care facility [.] or institution or provider has  
 188 previously obtained a certificate of need for the equipment [or  
 189 accelerator being] to be replaced;

190 (2) The replacement value or expenditure for the replacement  
 191 equipment [or accelerator] is not more than the original cost plus an  
 192 increase of ten per cent for each twelve-month period that has elapsed  
 193 since the date of the original certificate of need; and

194 (3) The replacement value or expenditure is less than two million  
 195 dollars.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>July 1, 2005</i>	19a-638(a)(4)
Sec. 2	<i>July 1, 2005</i>	19a-639(a)
Sec. 3	<i>July 1, 2005</i>	19a-639(b)(3)
Sec. 4	<i>July 1, 2005</i>	19a-639(c)
Sec. 5	<i>July 1, 2005</i>	19a-639a
Sec. 6	<i>July 1, 2005</i>	19a-639c

**PH**            *Joint Favorable Subst.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

### **OFA Fiscal Note**

#### **State Impact:**

Agency Affected	Fund-Effect	FY 06 \$	FY 07 \$
Health Care Access, Off.	GF - Cost	Minimal	Minimal
Health Care Access, Off.	GF - Revenue Gain	Potential Minimal	Potential Minimal
UConn Health Ctr.	GF - Cost	Potential Minimal	Potential Minimal

Note: GF=General Fund

**Municipal Impact:** None

#### **Explanation**

Passage of the bill may result in an increase in the number of certificate of need (CON) applications filed with the Office of Health Care Access (OHCA). While the exact number of additional CON reviews held each year cannot be determined in advance, it is expected that any resulting costs to the agency will be minimal and can be accommodated within its anticipated budgetary resources.

Pursuant to Section 19a-643(c), regulations of the OHCA must include a fee schedule for CON review under Section 19a-639 CGS. The fee schedule must (1) contain a minimum filing fee for all applications, (2) be based on a percentage of the requested authorization in addition to the minimum filing fee, and (3) apply to new requests and requests for modification of prior requests.

It cannot be determined at this time what fee would be imposed upon CON applications involving equipment costing less than \$400,000, as OHCA regulations presently do not address this potentiality. However, applicants currently filing CON requests under Section 19a-639 CGS are subjected to filing fees of \$400 when CON requests involve capital expenditures for major medical equipment,



imaging equipment or a linear accelerator costing more than \$400,000 but less than or equal to \$1 million. A filing fee of \$1,000 plus .05 percent of the total project cost is paid when an applicant seeks to make a capital expenditure in excess of \$1 million.

A potential cost would result for the University of Connecticut Health Center to the extent that it may be subjected to CON review, and applicable filing fees, related to the purchase or lease of equipment meeting criteria specified in the bill that would not presently be subject to CON review.

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**OLR Bill Analysis**

sSB 1207

**AN ACT CONCERNING THE CAPITAL EXPENDITURE THRESHOLD FOR THE REGULATION OF EQUIPMENT ACQUISITIONS****SUMMARY:**

This bill amends the certificate of need (CON) process by eliminating the capital expenditure threshold of \$400,000 for CON review of proposals involving the purchase or lease of various types of scanning equipment and linear accelerators. The bill specifies that equipment acquisitions involving CT scanners, PET scanners, PET/CT scanners, MRI scanners, cineangiography equipment, linear accelerators, or equipment with technology that is new or being introduced into the state will be subject to CON review, regardless of the proposed capital expenditure or capital cost associated with the CON proposal.

The bill provides exemptions and waivers from CON for the specific type of equipment listed above under certain conditions.

CON is a regulatory process, administered by the Office of Health Care Access (OHCA), for reviewing certain proposed capital expenditures by health care facilities, acquisition of major medical equipment, institution of new services or functions, termination of services, transfer of ownership, and decreases in bed capacity. Generally, CON approval is a formal statement by OHCA that a health facility, medical equipment purchase, or service change is needed.

EFFECTIVE DATE: July 1, 2005

**CERTIFICATE OF NEED*****CON for Certain Types of Medical Equipment***

By law, Connecticut health care facilities need to obtain a CON from OHCA prior to developing, expanding, or terminating certain services and expending more than \$1 million on a capital project. Additionally, a CON is required when a facility proposes to acquire major medical

equipment, imaging equipment, or linear accelerators with a capital cost in excess of \$400,000.

This bill retains the \$400,000 threshold for CON review of major medical equipment acquisition but subjects the purchase, lease, or donation of specific types of medical equipment to CON review regardless of cost. This equipment includes a CT scanner, PET scanner, PET/CT scanner, MRI scanner, cineangiography equipment, a linear accelerator, or other equipment utilizing technology that is new or being introduced into the state.

By law, the CON process begins when the applicant submits a letter of intent (LOI) to OHCA. Once the LOI is filed, the applicant receives a CON application form and is notified of the filing window for the application. The applicant must file the CON application between the 60<sup>th</sup> and 120<sup>th</sup> day from the LOI filing. A one-time 30-day extension may be requested by the applicant, extending the filing date to the 150<sup>th</sup> day. The bill specifies that OHCA must accept or reject the extension request within five business days from the date it receives the request.

### ***Public Hearings***

By law, OHCA must hold a public hearing on a completed CON application if (1) the proposal has associated total capital expenditure or total capital costs exceeding \$20 million for land, building, or non-clinical equipment acquisition; new building construction; or building renovation; (2) the proposal has associated total per-unit capital expenditures or capital costs exceeding \$1 million for major medical equipment, imaging equipment, or linear accelerators that use new technology or technology being introduced to the state; or (3) three individuals or one person representing an entity of five or more people submit a request in writing for a public hearing.

Under the bill, a public hearing must be held on completed CON applications involving scanning equipment, cineangiography equipment, linear accelerators, or any other equipment using technology that is new or being introduced into the state, regardless of the capital costs.

### ***Exemption From CON***

The bill provides an exemption from CON review for health care facilities proposing to purchase or lease the scanning or cineangiography equipment, or linear accelerator if the facility (1) provides OHCA with satisfactory evidence that it purchased or leased the equipment before July 1, 2005 and it was operating before that date or (2) obtained from OHCA, before July 1, 2005, a determination that a CON was not required for the purchase or lease of the equipment.

### ***Waiver of CON***

By law, a waiver of CON is considered when major medical equipment, imaging equipment or a linear accelerator that was previously authorized under a CON needs replacement. A waiver authorizes the replacement of the equipment without an additional CON. OHCA must review the request and supporting evidence, which must include the previously obtained CON for the equipment being replaced, documentation that the replacement cost is less than \$2 million, and a replacement expenditure not more than the original cost plus an increase of 10% for each 12 month period since the original CON. This bill specifies that OHCA may provide such waivers for replacement of scanning, cineangiography, and linear accelerator equipment.

## **BACKGROUND**

### ***Related Bills***

SB 1143 redefines “affiliate” for purposes of CON review and establishes a deadline by which a person seeking a public hearing on a CON application must make a request to OHCA. The Public Health Committee favorably reported this bill.

sSB 1145 makes several changes in the dates by which hospitals and other health care providers must submit applications or data to OHCA, who must submit data, and the data they must submit. It extends penalties for failure to file to a wider range of entities. It revises OHCA’s authority concerning hospital funds and eliminates a report OHCA must make on graduate medical education. The Public Health Committee favorably reported this bill.

### ***Scanning and Cineangiography Equipment***

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“Cineangiography equipment” records sequential x-ray images of the

heart and arteries after the selective injection of iodinated contrast medium. It is used to evaluate morphology, dimensions and function of the heart, and morphology of the great arteries. Cineangiography employs a cine camera to record the images from the image intensifier onto cine film.

A “CT (computerized tomography) scanner” is a special kind of x-ray machine. Instead of sending out a single x-ray through the body as with ordinary x-rays, several beams are sent simultaneously from different angles. CT scans are far more detailed than ordinary x-rays.

A PET (positron emission tomography) scanner” is a device that produces cross-sectional x-rays of metabolic processes by means of positron emission tomography. A PET scan combines CT and nuclear scanning. During a PET scan, a radioactive substance called a tracer is combined with a chemical (such as glucose); this mixture is generally injected into a vein. The tracer emits tiny positively charged particles (positrons) that produce signals. A PET scan can be used to study the brain’s blood flow and metabolic activity for example. It is also used to detect and evaluate cancer.

An “MRI (magnetic resonance imaging) scan” produces pictures of the inside of the body. Unlike an x-ray, an MRI scan does not use radiation. Rather, a magnetic field is used to make the body’s cells vibrate. They then give off electric signals which are interpreted by a computer and turned into very detailed images of “slices” of the body.

A “linear accelerator” is used for external beam radiation treatments for patients with cancer. It delivers a uniform dose of high-energy x-ray to the region of the patient’s tumor. These x-rays can destroy the cancer cells while sparing the surrounding normal tissue.

## **COMMITTEE ACTION**

Public Health Committee

Joint Favorable Substitute

Yea 24      Nay 0